

Notice of Allowability

Application No.

10/715,903

Examiner

Henry S. Hu

Applicant(s)

ANDERSSON ET AL.

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment of January 8, 2007.
2. ☒ The allowed claim(s) is/are 1-21,28,40,41 and 43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in two telephone interviews with **Karen A. Harding** (Registration No. 33,967, tel. 904 443-3074) on **February 22, 2007** to cancel non-elected Claims 22-27, 29-39, 42 and 44 as well as to amend Claim 28 as following:

Claim

Claims 22-27, 29-39, 42 and 44 please cancel Claims 22-27, 29-39, 42 and 44

Claim 28 at line 1 please insert a phrase of "having the percent haze at less than about 200%" between "lens" and "comprising"

DETAILED ACTION

Art Unit: 1713

2. This Office Action is in response to four things including **Amendment, Petition to Revival, Terminal Disclaimer and two 132 Declarations** all filed and/or approved on January 8, 2007. **Claims 1, 17-18, 28 and 40-41 were amended, while no claim was cancelled or added.** To be more specific, two parent Claims 1 and 28 were amended to add the advantage as "exhibiting, in the presence of viable bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log". Dependent Claims 17-18 and 40-41 were amended for clarification or cosmetic use.

With above Examiner's amendment, **non-elected Claims 22-27, 29-39, 42 and 44 (Groups II-VIII) are all cancelled and parent Claim 28 is amended to carry the same percent on the haze of lens as Claim 1.** The examiner thereby withdraws specification objection, claim objection and ODP claim rejection in the previous Office Action dated April 7, 2006. As pointed out earlier, the examiner **accepts Applicants' drawing in 18 sheets with 21 figures (Figures 1-21 with brief description on page 2).** **Claims 1-21, 28, 40-41 and 43 with two independent claims (Claims 1 and 28) are now pending** An action follows.

3. Claim rejections in previous non-final Office Action filed on April 7, 2006 are now removed for the reasons given in paragraphs 4-11 thereafter.

Allowable Subject Matter

4. Claims 1-21, 28, 40-41 and 43 are allowed.

Art Unit: 1713

5. The following is an examiner's statement of reasons for allowance: The above Claims 1-21, 28, 40-41 and 43 are allowed over the closest references:

6. The limitation of parent **Claim 1** in present invention relates to *an antimicrobial ophthalmic lens comprising a metal salt and having a percent haze of less than 200% and exhibiting, in the presence of viable bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log.* Other parent **Claim 28** relates to *two-stepwise method of producing an antimicrobial ophthalmic lens comprising a metal salt, wherein said lens exhibits, in the presence of viable bacteria or other microbes, a reduction of said viable bacteria or other microbes of at least about 0.5 log.* See other limitations of dependent **Claims 2-21, 40-41 and 43.**

7. Applicant has claimed now in each of two parent claims including **Claim 1 (composition) and Claim 28 (process of making)** an unexpected way of obtaining *an antimicrobial ophthalmic lens* exhibiting an advantage as, in the presence of viable bacteria or other microbes, *a reduction* of said viable bacteria or other microbes of *at least about 0.5 log.* The key point is that the lens comprises *a metal salt* and *having a percent haze at less than 200%.* It is noted parent Claim 28 is the process of making the same composition of Claim 1.

Art Unit: 1713

8. In a very close examination on pending 102 and/or 103 rejections, all involving references including **Rothore, Borowsky, Barry and McCabe**, alone or in combination, cannot stand now with current claim limitation as follows:

In view of the **first Declaration** written by Inventors Rathore and Anderson as well as the statement on page **10** at top section of Remarks, USPG-PUB 2004/0151755 A1 Rothore et al. with effective US filing date of December 21, 2000 and the same assignee thereby cannot be used as a prior art for 102(e) rejection according to MPEP.

9. In view of the **second Declaration** written by Inventors Vanderlaan as well as different results being obtained by repeating US 4,576,453 to Borowsky's procedure, such obtained lens from Borowsky indeed does not show a reduction of viable bacteria more than 0.5 log.

Although **Borowsky or Barry** may disclose the preparation of contact lens by adding some metal ion such as silver salt (AgX) or silver zeolite in the form as a solution into a hydrogel lens so that metal ion can be stayed within gel matrix and such a contact lens having silver ion may be for antimicrobial purpose. However, each reference is still **silent of two things as:** (A) the lens property having the percent haze at less than about 200%, and (B) a reduction of viable bacteria more than 0.5 log.

10. As pointed out by Applicants on pages 11 and 12 of Remarks, Barry provides no motivation to replace zeolites with the claimed metal salt, while McCabe does not disclose or suggest incorporating metal salts into a contact lens.

After further search, it is noted that **no search report is found for Applicants' PCT/US2003/037409 (WO 2004/047879 A2),**

11. After further examination and search, the examiner found the following prior art did not teach the claimed limitation:

US 5,520,910 to Hashimoto et al. (or its equivalent WO 95/02617 to Hashimoto et al.) only discloses an antimicrobial contact lens can be made from (A) **a polymer obtained by homo- or copolymerizing a phosphonium salt type vinyl monomer**, and (B) **a large quantity of an antimicrobial agent or a potent antimicrobial agent** (abstract, line 1-7; column 2, line 35-37). However, **metal salt is not disclosed or suggested**. The claimed percent haze and the claimed reduction of viable bacteria or other microbes are both not disclosed at all. Therefore, Hashimoto fails to teach or fairly suggest the copolymers of present invention.

US 6,815,074 B2 to Aguado et al. only discloses an ophthalmic antimicrobial contact lens useful for extended-wear periods can be made from (A) **a polymer obtained by polymerization of aoxypem macromer and an ionopem monomer** (abstract, line 1-10; column 2, line 35-37). Although lens haze is discussed (column 20, line 22-62), **metal salt is not disclosed or suggested adding into the lens composition**. The claimed percent haze and the claimed reduction of viable bacteria or other microbes are both not disclosed at all. Therefore, Aguado fails to teach or fairly suggest the copolymers of present invention.

Art Unit: 1713

12. The key issue on making an metal salt-containing antimicrobial ophthalmic lens so as to carry two properties as: (A) exhibiting a reduction of said viable bacteria or other microbes of at least about 0.5 log, and (B) the lens has a percent haze at less than 200%, cannot be overcome by any or the combination of the above references, therefore, the present invention is novel.


13. As of the date of this office action, the examiner has not located or identified any reference that can be used singularly or in combination with another reference including the above references to render the present invention anticipated or obvious to one of the ordinary skill in the art. Therefore, the two independent and parent **Claims 1 and 28** are allowed for the reason listed above. Since the prior art of record fails to teach the present invention, the remaining pending dependent **Claims 2-21, 40-41 and 43** are passed to issue.

14. Any inquiry concerning this communication or earlier communication from the examiner should be directed to **Dr. Henry S. Hu** whose telephone number is **(571) 272-1103**. The examiner can be reached on Monday through Friday from 9:00 AM –5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reached on (571) 272-1114. The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300** for all regular communications.


Art Unit: 1713

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry S. Hu

Patent Examiner, art unit 1713, USPTO

February 22, 2007


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